

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 6, “General Pharmacy Practice,” Iowa Administrative Code.

The amendments were approved at the August 28, 2013, regular meeting of the Board of Pharmacy.

The proposed amendments add to the information that must be communicated to the pharmacist receiving a prescription transfer from another pharmacy any special directions, restrictions, or notations included by the prescriber on the original prescription including but not limited to restrictions relating to drug product selection or substitution. The amendments also add new rule 657—6.11(155A) establishing requirements for drug product selection and “do not substitute” restrictions.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on October 22, 2013. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail to terry.witkowski@iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 155A.13, 155A.27, 155A.32, and 155A.34.

The following amendments are proposed.

ITEM 1. Amend paragraph **6.9(8)“b”** as follows:

b. Record on or with the transferred prescription drug order the following information:

(1) to (6) No change.

(7) Name of the pharmacist or pharmacist-intern transferring the prescription drug order information; ~~and~~

(8) If transferring a controlled substance prescription from a pharmacy utilizing a shared electronic database system as described in subrule 6.9(9) to a pharmacy outside that shared system, the pharmacy name, location, DEA registration number, and prescription number from which the prescription was originally filled-; ~~and~~

(9) Any special directions, restrictions, or notations of the prescriber including, but not limited to, “dispense as written” or “do not substitute.”

ITEM 2. Adopt the following new rule 657—6.11(155A):

657—6.11(155A) Drug product selection. Except as provided herein, a pharmacist may exercise professional judgment in the economic interest of a patient by selecting a drug product with the same generic name and demonstrated bioavailability as the drug prescribed for dispensing and sale to the patient. If the pharmacist exercises drug product selection, the pharmacist shall inform the patient of the substitution, the reason for the substitution, and any savings realized by the patient as a result of the substitution.

6.11(1) Substitution prohibited. A pharmacist shall not exercise drug product selection described herein if either of the following is true:

a. The prescriber specifically indicates, in any manner, that no drug product selection shall be made or that only a specified drug product may be dispensed. Prescriber directions prohibiting substitution may include, but are not limited to, the following:

- (1) Manually signing a prescription on a line that indicates substitution is not authorized.
- (2) Checking a box on a prescription that indicates substitution is not authorized.
- (3) Specifically indicating on the face of the prescription that no substitution is authorized.
- (4) Including the phrase “brand name necessary,” “dispense as written,” or “DAW” on the face of the prescription.
- (5) Indicating in text on the prescription that only a specific product or a specific manufacturer’s product may be dispensed.

b. The patient or patient’s agent presenting the prescription for filling indicates that no substitution shall be made. However, if the cost or any part of the cost of the prescription will be paid by expenditure of public funds authorized under the Iowa Medical Assistance Act (Iowa Code chapter 249A), this paragraph shall not apply.

6.11(2) *Prescriber consultation.* If a pharmacist is unable to provide the specific drug authorized by a prescriber due to unavailability of the product, and if the prescriber has indicated that substitution is not authorized or has indicated that only a specific product is authorized, the pharmacist shall contact the prescriber to explain the situation and to discuss alternatives. The pharmacist shall note on the prescription record the date of the consultation with the prescriber and the results of that consultation. The pharmacist shall not dispense a substitute product without verbal authorization of the prescriber. The pharmacist may, however, exercise professional judgment by filling a prescription without prescriber authorization if the pharmacist is unable to contact the prescriber after reasonable effort, the pharmacist determines that failure to fill the prescription might result in an interruption of therapeutic regimen or create patient suffering, and the pharmacist informs the patient at the time of dispensing and the prescriber as soon as possible that prescriber reauthorization is required.

6.11(3) *Record of substitution* If the pharmacist selects a generically equivalent product pursuant to this rule, the pharmacist shall note that fact, including the name of the manufacturer of the selected product or the national drug code of the specific product dispensed, on or with the prescription dispensing record.

ITEM 3. Amend **657—Chapter 6**, implementation sentence, as follows:

These rules are intended to implement Iowa Code sections 124.301, 124.303, 124.306, 126.10, 126.11, 155A.6, 155A.13, 155A.27, 155A.28, and 155A.31, ~~and 155A.33~~ through 155A.36.